

R E M A R K S

Claim Amendments

Claims 20 to 22 were canceled.

Claims 23 to 26 were amended into independent form by including the features of claim 20.

Objection Under 37 CFR 1.75(c)

Claims 23 to 26 were objected to under 37 CFR 1.75(c) as being in improper form because they depended on a multiple dependent claim (see the bottom of page 4 of the Office Action).

As discussed above, claims 23 to 26 were amended into independent form.

In view of the above, withdrawal of the objection to claims 23 to 26 is respectfully requested.

Rejection Under 35 USC 112, First Paragraph

Claims 21 and 22 were rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth beginning at the top of page 5 and continuing to the top of page 8 of the Office Action.

As discussed above, claims 21 and 22 were canceled. The 35 USC 112, first paragraph rejection is thus moot.

Withdrawal of the 35 USC 112, first paragraph rejection is respectfully requested.

Anticipation Rejection Under 35 USC 102

Claims 20 and 21 were rejected under 35 USC 102 as being anticipated by Inohara et al. (WO 2003/013612) (English-language equivalent of US 2004/0266725) for the reasons set forth on page 8 of the Office Action.

It is noted that claims 23 to 26 were not included in the 35 USC 102 rejection.

As discussed above, claims 21 and 22 were canceled. The 35 USC 102 rejection is thus moot.

Withdrawal of the 35 USC 102 rejection is respectfully requested.

Presently Claimed Invention

The presently claimed invention is directed to a polysaccharide-containing composition comprising (i) a polysaccharide selected from the group consisting of agar,

agarose, agarpectin, galactan, carageenan, tamarind gum, tara gum and gellan gum and (ii) water, wherein the concentration of said polysaccharide is 0.0001 to 0.01 wt%, and an amount of precipitated polysaccharide after performing centrifugal separation at 25°C with 40,000  $\times g$  for one hour is less than 65 wt% of a total polysaccharide content (see applicants' claim 1).

The presently claimed invention also pertains to an agar-containing ophthalmic solution characterized by stabilizing a tear film on an eyeball surface, wherein:

(i) the content of agar is 0.0001 to 1 wt% (see applicants' claim 23);

(ii) the content of agar is 0.001 to 0.5 wt% (see applicants' claim 24);

(iii) the agar has a weight average molecular weight of 10,000 to 1,000,000 (see applicants' claim 25);

(iv) the viscosity of the ophthalmic solution measured in an E type viscosity at 25°C and a shear rate of 100  $s^{-1}$  is 30 mPas or lower (see applicants' claim 26).

Obviousness Rejections Under 35 USC 103

Claims 1 to 3, 6 to 8 and 19 to 22 were rejected under 35 USC 103 as being unpatentable over Inohara et al. (WO 2003/013612) (English-language equivalent of US 2004/0266725) in view of Bourlais et al., "Ophthalmic Drug Delivery Systems-Recent Advances," Progress in Retinal and Eye Research, Vol. 17, No. 1, (1998), pp. 38 to 58 and further in view of Van Santvliet et al., "Influence of the physico-chemical properties of ophthalmic viscolysers on the weight of drops dispensed from a flexible dropper bottle," European Journal of Pharmaceutical Sciences, 7, (1999), pp. 339 to 345 for the reasons set forth beginning at the top of page 9 and continuing to the top of page 12 of the Office Action.

The following admissions were in the first paragraph on page 10 of the Office Action:

"Inohara et al. does not specifically teach the concentration of said polysaccharide is 0.0001 to 0.01 wt% and the amount of precipitated polysaccharide after performing centrifugal separation at 25°C with 40,000 xg for one hour (instant claim 1). Inohara et al. does not specifically disclose the composition being operable to be uniformly dispersed on a mucous membrane when topically administered to a mammal (instant

claim 6) and wherein the mucous membrane is an ocular mucous membrane (instant claim 7). Inohara et al. does not specifically teach the composition as a contact lens-wearing solution or a contact lens preservative solution (instant claim 19). Inohara et al. does not specifically teach the amount of precipitated polysaccharide after performing centrifugal separation at 25°C with 40,000 xg for one hour and the composition being characterized by uniformly dispersing on an ocular surface when administered in the eye (instant claim 22)."

The following is stated on page 20, lines 18 to 23 of the present specification:

"...when agar is in the gel state, a hydrogen bonding is formed between molecular chains of agar molecules so that the agar molecules incorporate water molecules to establish a helical structure, thereby achieving a higher-order and stronger structure and being precipitated by centrifugation."

The state of agar and the like in the composition described in Inohara et al. corresponds to that of the above description. In other words, agar and the like exist as molecules in a gel form. This is also clear from the Comparative Examples 3 and 4 on pages 23 to 24 of the present specification (equivalent to the composition described in Inohara et al.). Comparison Examples 3

and 4 have a significant high ratio of precipitated agar (%) of 67.2% and 74.8%, respectively (see Table 1 on page 26 of the present specification).

The following is stated on page 20, line 23 to page 21, line 6 of the present specification:

"In turn, some of the agar molecules existing in the water-based medium are highly free and hydrous without forming the stable helical structure, and such agar molecules are not precipitated by centrifugation. When a liquid containing such agar molecules is administered on the ocular mucous membrane surface, the agar molecules spread widely on the ocular mucous membrane surface to exhibit the tear fluid stabilizing effect."

The state of agar and the like in the presently claimed invention corresponds to that of the above description. In other words, agar and the like exist as highly free molecules in the presently claimed invention. This is clear from the present Example 2 showing a significantly low number for the "ratio of precipitated agar (%)" of  $\leq 0.1$  (see Table 1 on page 26 of the present specification).

As discussed above, in the presently claimed invention, agar and the like spread widely on an ocular mucous membrane surface

to exhibit a significant tear fluid stabilizing effect by existing as highly free molecules.

In contrast to the presently claimed invention, none of the cited references including Inohara et al. teach or suggest that agar and the like in a composition exist as highly free molecules to obtain a significant tear fluid stabilizing effect.

Therefore, it is respectfully submitted that one having ordinary skill in the art would not arrive at the presently claimed invention exhibiting a significant tear stabilizing effect, even if the references including Inohara et al. were combined.

Withdrawal of the 35 USC 103 rejection is respectfully requested.

#### Obviousness-Type Double Patenting Rejection

Claims 20 and 21 were provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over amended claims 1, 3, 5, 7 and 9 to 11 of copending related application Serial No. 11/810,524 for the reasons set forth beginning at the bottom of page 12 and continuing to the middle of page 13 of the Office Action.

It is noted that claims 23 to 26 were not included in the obviousness-type double patenting rejection.

As discussed above, claims 20 and 21 were canceled. Accordingly, the obviousness-type double patenting rejection is moot.


Withdrawal of the obviousness-type double patenting rejection is respectfully requested.

Reconsideration is requested. Allowance is solicited. The USPTO fee of \$220 for an additional independent claim is being paid by credit card herewith. Any additional fees or overpayments are hereby authorized to be charged to Deposit Account No. 06-1378.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

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Respectfully submitted,

  
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